

REMARKS

In the specification, the paragraphs at page 2, line 19 to page 3, line 14; at page 5, lines 18-22 and 25-26, and Table 2 at page 7, line 10 to page 8 have been amended to correct minor editorial errors.

Claims 8, 10 and 11 have been amended. Support for the amendment can be found throughout the specification, especially at page 6, line 9 ("Gram-stain: positive") and page 26, line 6 and page 32, line 1 (dosage of 10^9 CFU/mL). Claim 11 is amended to correct a minor typographical error. No new matter is added. Claims 1, 2, and 8-12 remain in this application. No claims are canceled.

Rejection of claims 1, 2, and 8-12 under 35 U.S.C. 112, second paragraph

Claims 1, 2, and 8-12 stand rejected under 35 U.S.C. 112, second paragraph for allegedly failing to assure that all required deposits of *Lactobacillus rhamnosus* GM-020 have been made under the provisions of the Budapest Treaty. Applicants respectfully submit a signed Declaration by applicant stating that the deposit has been accepted by the International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application. Therefore, the rejection is overcome. It is respectfully submitted that the rejection be withdrawn.

Rejection of claims 1, 2, and 8 under 35 U.S.C. 102(b) or 35 U.S.C. 103(a) over Gill (WO 99/10476)

Claims 1, 2, and 8 stand rejected under 35 U.S.C. 102(b) as being anticipated by Gill or, alternatively, under 35 U.S.C. 103(a) as being unpatentable over Gill. These rejections are respectfully traversed.

Claim 1 recites an isolated microorganism of the strain *Lactobacillus rhamnosus* GM-020, deposited at the China Center for Type Culture Collection under CCTCC No.: CCTCC M 203098. Gill discloses *Lactobacillus rhamnosus* HN001 and HN067 which are distinct from *Lactobacillus rhamnosus* GM-020 of claim 1. For example, Gill discloses that *Lactobacillus rhamnosus* HN001 and *Lactobacillus rhamnosus* HN067 have scores of 5757177 and 5757175 on testing with the API 50 CH sugar fermentation kit, respectively. See Gill, page 7, Table 2. In contrast, *Lactobacillus rhamnosus* GM-020 has a score of 5776175 on testing with the API 50 CH sugar fermentation kit. Applicants submit data from testing with the API 50 CH sugar fermentation kit for *Lactobacillus rhamnosus* GM-020 of claim 1. The test results demonstrate that *Lactobacillus rhamnosus* HN001 and *Lactobacillus rhamnosus* HN067 ferment different sugars than *Lactobacillus rhamnosus* GM-020. Thus, neither *Lactobacillus rhamnosus* HN001 nor *Lactobacillus rhamnosus* HN067 are the same as *Lactobacillus rhamnosus* GM-020. Because Gill fails to teach or suggest *Lactobacillus rhamnosus* GM-020, the rejection of claim 1 under 35 U.S.C. 102(b) should be withdrawn.

The Patent office concedes that Gill fails to teach a composition comprising *Lactobacillus rhamnosus* GM-020 but asserts that it would allegedly have been obvious to one of ordinary skill in the art to “include the bacteria[1] strains of Gill ... because the *Lactobacillus rhamnosus* of Gill et al

appear to be the same as the claimed *Lactobacillus rhamnosus* bacteria.” Office Action dated October 20, 2004, page 7, lines 1-3. As set forth above, the *Lactobacillus rhamnosus* of Gill is not the same as the claimed *Lactobacillus rhamnosus* GM-020.

Moreover, it is well known in the art that different strains of an organism, even if classified within the same species, do not always possess identical characteristics or properties. For example, it is well known that some strains of *E.coli* are probiotics (*i.e.*, promote the growth of organisms) whereas some strains of *E.coli* are toxic. For example, *E.coli* strain Nissle 1917 (O6:K5:H1) is a commensal organism and has a long tradition in medicine for the treatment of various intestinal disorders in humans. In contrast, *E. coli* O157:H7 causes hemorrhaging and may lead to death. Thus, one of ordinary skill in the art would not have been able to predict the properties of *Lactobacillus rhamnosus* GM-020 based solely on the properties of other strains of the same species (*e.g.*, HN001 or HN067). Therefore, the rejection should be withdrawn.

Claims 2 and 8 depend from claim 1 and are allowable for at least the reasons set forth above for claim 1.

Rejection of claims 1, 2, and 8 under 35 U.S.C. 102(b) or 35 U.S.C. 103(a) over Bukowska (WO 99/07827)

Claims 1, 2, and 8 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bukowska (WO 99/07827) or, alternatively, under 35 U.S.C. 103(a) as being unpatentable over Bukowska (WO 99/07827). These rejections are respectfully traversed.

Claim 1 recites an isolated microorganism of the strain *Lactobacillus rhamnosus* GM-020, deposited at the China Center for Type Culture Collection under CCTCC No.: CCTCC M 203098.

Bukowska (WO 99/07827) discloses *L. casei* spp. *rhamnosus* 271 (page 4, lines 16-17) and a food product (ProViva®) containing *Lactobacillus plantarum* 299v (page 5, lines 13-15). Bukowska (WO 99/07827) fails to disclose *Lactobacillus rhamnosus* GM-020. Thus, Bukowska (WO 99/07827) fails to teach each and every aspect of claim 1. The rejection of claim 1 under 35 U.S.C. 102(b) should therefore be withdrawn.

The Patent Office concedes that Bukowska (WO 99/07827) fails to teach or suggest a composition comprising *Lactobacillus rhamnosus* GM-020. However, the Patent Office asserts that it would have been obvious to one of ordinary skill in the art to “include bacteria strains of Bukowska et al in a composition because *Lactobacillus* [spp] of Bukowska et al appear to be the same as the claimed *Lactobacillus rhamnosus* bacteria and can be used to reduce cholesterol level.” Office Action dated October 20, 2004, page 7. However, the *Lactobacillus* spp. of Bukowska are not the same as the claimed *Lactobacillus rhamnosus* GM-020. As set forth above, different strains of an organism, even if classified within the same species, do not always possess identical characteristics or properties (e.g., *E. coli* strain Nissle 1917 (O6:K5:H1), a commensal organism, vs. *E. coli* O157:H7, an organism that causes death).

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Bukowska fails to meet all limitations of claim 1. Therefore, it is respectfully submitted that claim 1 defines patentably

distinct subject matter. The rejection should therefore be withdrawn.

Claims 2 and 8 depend from claim 1 and are allowable for at least the reasons set forth above for claim 1.

Rejection of claims 1, 2, and 8-12 under 35 U.S.C. 103(a) over Bukowska in view of Tamaki (Mokuzai Gakkaishi, March 1997, Vol. 43, No. 1, p. 90-95) or Yang (Biotechnology Letters, August 2002, Vol. 24, No. 16, p. 1319-1325)

Claims 1, 2, and 8-12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bukowska (WO 99/07827) in view of Tamaki or Yang. This rejection is respectfully traversed.

Claims 1, 2, and 8-12 recite an isolated microorganism of the strain *Lactobacillus rhamnosus* GM-020, deposited at the China Center for Type Culture Collection under CCTCC No.: CCTCC M 203098. As set forth above, Bukowska teaches *Lactobacillus plantarum* but fails to teach or suggest *Lactobacillus rhamnosus* GM-020. Tamaki and Yang also fail to teach or suggest *Lactobacillus rhamnosus* GM-020. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Since none of the cited prior art teaches *Lactobacillus rhamnosus* GM-020, the Patent Office has failed to make a *prima facie* case of obviousness. Therefore, the rejection should be withdrawn.

Even if, *arguendo*, Tamaki or Yang disclose that *Auricularia polytricha* lowers cholesterol and even if the prior art taught that *Lactobacillus rhamnosus* lowers cholesterol, Applicants have, for the first time, demonstrated unexpectedly advantageous and superior results through the combination of *Auricularia polytricha* and *Lactobacillus rhamnosus* GM-020. "In one experiment ... the body

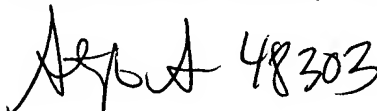

weight of the [obese] animal model with a treatment with combination of wood ear [*Auricularia polytricha*] and GM-020 was reduced; to the contrary, the administration of wood ear or GM-020 solely can inhibit body weight gain only." Hence, administration of either agent alone results in inhibition of weight gain but no weight loss. Specification at page 20, lines 8-11. Even if *Lactobacillus rhamnosus* GM-020 was known in the prior art (no evidence has been adduced to that effect), it would have been wholly unexpected that the combination of *Auricularia polytricha* and *Lactobacillus rhamnosus* GM-020 would result in reduction in body weight rather than mere maintenance of body weight. Such results are greater than that which would have been expected from the effect of each alone and provide an unexpected advantage. Therefore, for this reasons, too, the rejection should be withdrawn.

Applicants respectfully submit that the instant application is in condition for allowance. If the Examiner feels, however, that further amendment and/or discussion may be helpful in facilitating prosecution of the case, the Examiner is respectfully requested to telephone the undersigned attorney of record at the number appearing below.

Respectfully submitted,

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